



# **Final Project Report**

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## 1. Executive Summary

Project SLAM, Standardisation of Laboratory Analytical Methods, was a support and coordination activity with the objective to review the needs for standardisation of CBRN sample analysis at European laboratories. The outcome of the project is a roadmap to standardisation in this field. All partners in the SLAM consortium are significant players in the on-going dialogue on CBRN analytical requirements and procedures on the European scene. The composition of this consortium was well-balanced with regards to the complementary nature of the partners' capabilities.

SLAM has reviewed commonalities in relevant standards and procedures through thorough background studies of needs and available procedures for CBRN sampling, transport and analysis. In addition, procedures specific to the so-called "unknown sample", *i.e.* samples possibly containing one or more CBRN substances, have been reviewed and assessed. Workshops for discussions and tutorial inter-calibration exercises with European Union member states have been organised in order to widen the dialogue on standardisation and to find a common understanding of the needs and of the way ahead.

At the end of the project a roadmap with a suitable strategy towards common and appropriate analytical methods and related procedures was presented in order to enable the implementation of necessary standardisation measures and to create a harmonized and co-operative network of CBRN analysis laboratories in Europe.

A functional standardisation of CBRN analysis at the necessary level of stringency is an important component of a European Union that is more resilient to CBRN incidents.

## 2. Summary description of project context and objectives

One of the key requirements for CBRN preparedness and resilience in Europe is the capability to identify CBRN agents that might be used in terrorist attacks. Therefore, there is a growing need for laboratories that can perform quality analyses of biomedical and environmental samples under various circumstances, e.g. fast analysis to support the immediate incident response, mass screening during post-incident monitoring or highly specific forensic agent profiling. In addition, considering the risk of cross-border incidents or a lack of specific laboratory capacities in single EU member states, it is also important to link and to harmonize the existing capacities. This means not only that sampling and analysis procedures need to be validated, but also that there should be a common understanding of best practices, quality assurance measures, and even of organisational structures in order to allow for comparability of results and complementarity of analytical capacities in EU member states.

Analytical and diagnostics laboratories that are capable of performing prompt and accurate analysis of CBRN-relevant material are a vital component of our society in becoming more resilient to major incidents involving these compounds. With the advent of a structured approach to pan-European preparedness against CBRN incidents, there is an ever increasing demand on standardisation of processes, methods and equipment. This, obviously, includes the needs to standardize and to harmonize laboratory procedures.

In general terms, standardisation of a laboratory by an ISO standard, for example ISO 17025, means that the management and its responsibilities, the staff and its competence, the equipment and their calibration procedures and methods as well as their validation are well described and documented. In other words, you standardise the whole system and thus ensure that analytical results are correct and comparable to the results from other standardised laboratories. This is normally how modern hospitals and environmental laboratories are standardised today.

The use of CBRN threat agents is an international crime and several highly stringent regimes have been developed in order to assess, whether or not CBRN agents are used in breach of international or national laws. Some examples of such regimes are the *NATO handbook for Sampling and Identification of Biological and Chemical Agents* (SIBCRA AEP-10) and the *Blue Book of the Finnish Institute for Verification of the Chemical Weapons Convention* (VERIFIN), which have largely been adopted as standard procedures for the *Organisation for the Prohibition of Chemical Weapons* (OPCW). Such “standardisation” focuses only on some aspects of the full concept of standardisation described above. Having a forensic character, elements like chain of custody and documentation are high-lighted. In such not fully standardised regimes,

annual validation of laboratory performance using inter-calibration exercises are an important quality control.

The subject of analytical laboratory standardisation on a European level was discussed in 2004, when the hitherto most comprehensive and up-to-date report on the subject was issued by the IMPACT project (*Innovative Measures for Protection against CBRN Terrorism*, PASR-2004). Today there is a growing need for laboratories to perform quality controlled analysis of CBRN samples also outside the forensic type of investigation mentioned above. Laboratories might for example be needed to support cross-border activities in the wake of CBRN incidents. Another development is that analytical laboratories are asked to support the development of procedures and equipment, as illustrated by the CREATIF project (*Network of Testing Facilities for CBRNE detection equipment*, FP7), where standardisation of detection systems for CBRNE agents is intimately linked with appropriate laboratory validation. Another example is the ORCHIDS project (*Optimization through research of chemical incident decontamination systems*, DG SANCO), which has delivered quantitative evidence to support the development of optimal procedures for mastering mass casualty decontamination scenarios, for pan-European implementation. Other projects concerned with standardisation issues are FP7 projects like CBRNemap (*Road mapping study of CBRNE demonstrator*) and DECOTESSC 1 (*Demonstration of counter terrorism system of systems against CBRNE phase 1*), which encompass the full spectrum of crisis management activities required in the context of CBRNE terrorism.

Recently, a structured approach to the need for a unified view on quality control of CBRN analysis was highlighted in the 2009 report from the European Security Research & Innovation Forum (ESRIF). The CBRN workgroup recommended that: *“EU should create of a network of laboratories for forensic analysis and agent identification. ... Sampling and identification methods should be improved and include proper forensic aspects. A network of certified testing laboratories should be established capable of forensic level analysis complementary and in co-operation with proper national traditional forensic laboratories. In addition, there is a need for standardized protocols involving not only sampling and identification procedures but also standards for transport of samples.”*

Similarly, the EU CBRNE Action Plan discussed the relative importance of standardisation of analytical procedures from sampling to laboratory identification.

In the context of the above discussions and findings project SLAM, Standardisation of Laboratory Analytical Methods, is a support and coordination activity within the European Commission's Seventh Framework Programme with the ultimate goal to provide the EC with a roadmap to standardisation proposing strategies for implementation of a European quality control system for the complete analytical

process of CBRN samples, from sampling to data interpretation. The project applies a systems view to the needs and means for standardisation of CBRN sample analysis at European laboratories and authorities involved.

The objectives for the SLAM team are to review the needs for standardisation of CBRN sample analysis and to suggest a roadmap for implementation of such standardisation. The work is based on previous and ongoing initiatives, e.g. IMPACT, CREATIF, ORCHIDS, QUANDHIP (Quality assurance exercises and networking on the detection of highly infectious pathogens) as well as on analysis methods and procedures available at European laboratories. An important component of the project is a series of workshops with stakeholders from EU Member States. These workshops are intended to widen the dialogue on harmonisation and standardisation; existing standards, commonalities and best practices along with gaps are identified on different levels and for different analytical purposes, and the feasibility of possible solutions is discussed. During this work particular attention is given to handling of so-called “unknown” or mixed samples, i.e. samples that might contain one or more CBRN threat agents.

Standardisation of CBRN analysis at the necessary level of stringency will simplify cross-border cooperation and be an important component of European resilience against a CBRN crisis. The SLAM consortium consisting of significant players with regard to CBRN analytical capabilities takes the lead in the ongoing dialogue on standardisation and facilitates a valuable opportunity for in-depth networking of key European CBRN laboratories.

The objectives of the project as stated in the description of work were to:

- To suggest and seek agreement between EU 27 on differential needs for CBRN laboratory standards.
- To motivate and initiate a discussion on different CBRN networks depending on role and requirement of laboratories.
- To engage and educate relevant laboratories in EU 27 of inter-calibration exercises for CBRN analytical laboratories as requested in the call.
- To produce a road-map for correct and efficient standardisation of the European CBRN laboratory capability as requested in the call.

### 3. Description of the main S&T results

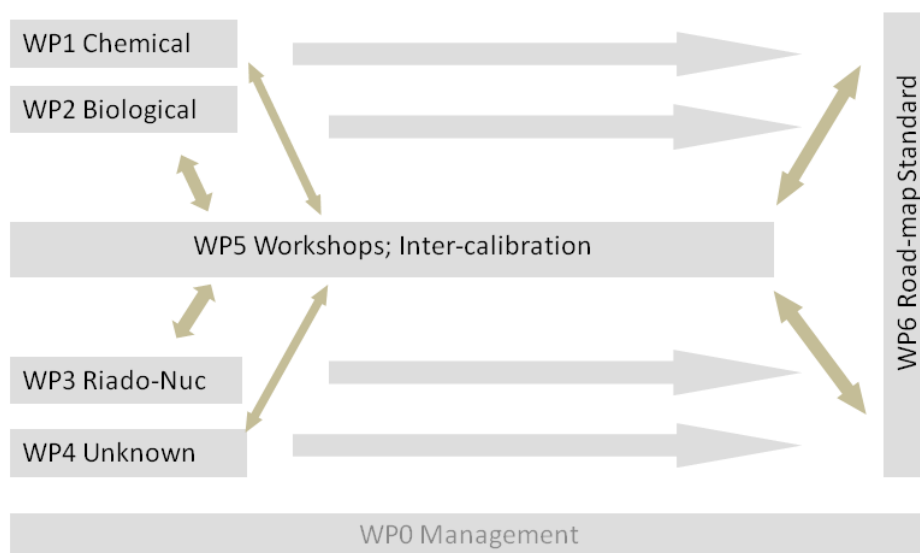
The discussion on standards of CBRN analytical procedures is fragmented. Each “letter”, each compound, has its own needs and has, accordingly, developed its own culture and views on standards and on quality control regimes such as Good Laboratory Practise. As has frequently been pointed out this fragmentation is problematic and may jeopardize the resilience of our society towards accidents or acts of terror involving CBRN. Project SLAM has therefore applied a systems view on the needs to standardise and on the purpose for standardisation of CBRN analysis. This systems view will, naturally, also become of value for research activities in this area.

The partners to the SLAM consortium are all key players in their respective national and/or international capabilities. Accordingly, they all possess large experience from the value of quality control and standardized analytical procedures for the purpose of best serving security related operations. The SLAM consortium is equally well positioned to overview the field of security research related to and relevant for analysis of CBRN related analytical methodology in Europe. Throughout the work on this support and coordination activity the SLAM partners have drawn from their own experience, from their contact networks and from the numerous stakeholder organisations that were engaged in the project’s workshops or the initial capability survey. Based on their experience, knowledge exchange, and past and present research efforts, the SLAM team has formulated a roadmap towards future policies and decisions to standardise the area of CBRN analysis.

Project SLAM was set up in six technical work packages focusing on the requirements for chemical, biological and radio-nuclear analysis, WPs 1-3 respectively, as well as on those for the analysis of mixed threat samples (WP4), on engaging member states (WP5) and on formulating the roadmap to standardisation from the combined project results (WP6, see Fig. 1). The overarching coordination of the work and administration of the project was provided by WP10, which also facilitated harmonisation of the efforts in WPs 1-3 early on in the project (*Project management*).

In order to apply a systems view of the European CBRN analytical capability, WPs 1-3 followed a well-aligned structure when identifying the needs for standardisation in the areas of chemical, biological and radio-nuclear analysis. These three work packages generated an overview of European laboratories analysing CBRN substances and of background materials like CBRN threat agents, existing procedures and protocols relevant for the handling and analysis of these threat agents. Their efforts also generated an overview and comparison of different standard regimes for the full analytical cycle, i.e. from sampling to the interpretation of data. Transportation regulations, guidelines and systems-in-place among European laboratories were also part of the background material needed for the final road-map.





*Figure 1: SLAM work packages and their interaction*

WP4 illustrated relevant cases of mixed or unknown samples, i.e. samples that might contain one or more CBRN threat agent. Based on input from WPs 1-3, WP4 created an inventory of the various methods that have been developed for the transport, handling and analysis of such unknown samples.

WP5 collated the efforts of the previous work packages and developed a workshop programme based on that information. At the first workshop the project partners analysed the outputs of WPs 1-4 with regard to threat agents, analytical procedures and laboratory capabilities together with representatives from member states laboratories. Suitable standard operating procedures, best practices and issues relevant to monitoring, alert and local/national response were discussed.

The second workshop further promoted engagement in standardisation issues and addressed crisis managers and national authorities from member states. The output of the previous workshop was tested, and knowledge and practices regarding the organisation of national crisis management capabilities were exchanged, with an emphasis on the need for and the role of various types of laboratories. The discussions in both workshops were based on specifically designed scenarios that captured a broad range of capabilities and cross-border cooperation. Results from the technical work packages and from the workshops, which also include the identification of obstacles to the harmonisation of CBRN sample analysis between European laboratories, formed the basis for the draft roadmap to standardisation, which was presented at the final stakeholder event. The feedback from the workshop delegates, i.e. representatives from

national and EU authorities, assisted then in finalizing the roadmap to systematic standardisation of the European CBRN analytical capability. One of the challenges to move towards harmonization of laboratory analysis lies in the complexity of many procedures, which have often been developed in-house for a specific objective. Validation of such procedures by using commonly accessible standardized control reagents (reference material) and through inter-laboratory comparisons and proficiency tests was thus identified as an important step towards a European network of qualified and compatible cooperating laboratories, thereby improving resilience against cross border and large scale CBRN incidents.

In the following we present the findings and suggestions from the various work packages in more detail.

### **3.1 Gaps and needs for chemical, biological and radio-nuclear analysis**

To align the work in WPs 1-3 and to apply a systems view to standardisation issues the project management organised an internal workshop, at which the complete project team together

- excluded routine monitoring of drinking water and food for quality assurance from the scope of SLAM;
- agreed to base the work as much as possible on intentional or accidental CBRN scenarios;
- established criteria for selecting representative CBRN-relevant agents such as putative impact in case of accidental or intentional release, availability and ease of weaponization, putative sample matrices, analytical requirements and need for standardisation;
- agreed on three principle purposes of the sample analyses that direct the needs for analytical capabilities in terms of speed, quality and quantity: i) for operational use to support the immediate incident response, ii) for monitoring and contingency purposes with mid- and long-term perspective, and iii) for agent profiling and forensic use in support of criminal investigations; and
- defined the relevant sample types to be i) the neat agent; ii) environmental matrices like air/aerosol, water, soil/sediment, powder, filter material from ventilation systems, surface swabs as well as vegetation and produce (milk, fish) in cases of post incident monitoring of contamination levels in food sources; and iii) biomedical samples like urine, faeces, blood, saliva or transpired fumes from casualties.

### 3.1.1 Threat agents

The three WP teams first decided upon the threat agents, which were considered to be most relevant in a CBRN setting, could represent groups of agents requiring similar procedures and which then guided the upcoming work. The lists of selected agents are briefly described below (for details see deliverables D1.1, D2.1, D3.1).

For chemical threat agents the selection was based on criteria such as toxicity, availability, ease of release and stability in the environment. A list of such chemicals included in a document from the United States Environmental Protection Agency on standardisation of analytical methods showed the largest overlap with other existing lists from previous studies. This list was evaluated and used to compile a SLAM list, in which some 90 threat agents were categorized into chemical warfare agents (CWA) and toxic industrial chemicals or related compounds (TIC). It was decided to exclude household chemicals from further considerations within project SLAM, since the possibility that they will be part of a high impact CBRN event was thought to be low. The CWA-related compounds were grouped into live agents, precursors and degradation products. TICs were divided into organic and inorganic chemicals. A colour code was applied according to the agent's physical state, gas, liquid or solid, at standard conditions.

The WP2 team selected nine species of bacteria and viruses for their high contagiousness, low infectious dose, good stability in the environment and high probability of intentional release in combination with the need for standardisation of analytical procedures in environmental matrices. These biological threat agents were seen as representatives of groups of agents with similar properties and demands on sample preparation and identification analysis in matrices like aerosol, water, soil, powder, fomites and surface swabs.

Radionuclides were prioritized according to the likelihood with which they might need to be identified in samples from radiological or nuclear accidents or terrorist attacks. The selection was based on three scenarios designed to cover a broad range of required analytical capabilities: i) nuclear power plant accident, ii) radioactive source dispersal, and iii) illicit trafficking of nuclear material. In these scenarios fission products, activation products and actinides are the most likely radionuclides to be encountered.

### 3.1.2 Laboratories

Different types of laboratories were identified depending on their capabilities and necessity for the three purposes of analysis

- i) Only OPCW-designated laboratories have the capability to analyse CWA agents and their precursors and are allowed to possess reference material. Various international networks of biological laboratories arrange proficiency

tests as a means of quality assurance (NATO SIBCRA, QUANDHIP, EBLN/*European biodefense laboratory network*)

- ii) Public health laboratories will be able and responsible to identify chemical, biological and radio-nuclear threat agents in environmental and biomedical samples. Different laboratories may be involved for the different categories of biological agents, but all should have appropriate biosafety facilities.
- iii) Forensic laboratories are needed in cases of terrorist attacks or if criminal intent is suspected. These laboratories will focus on agent profiling in order to identify the source and way of production of the agent and thus to assist law enforcement in convicting the perpetrator.
- iv) Laboratories capable of analysing large numbers of samples.
- v) Reference laboratories, in the B area often limited to specific biological agents.

### 3.1.3 Analytical procedures

Existing protocols for sampling, sample preparation and identification analysis of the selected threat agents were collected and reviewed. This work is in detail documented in deliverables D1.2, D2.2 and D3.2 and summarized in the following.

For chemical samples many analytical techniques are available in databases published by for example the *United States Occupational Safety and Health Administration (OSHA)* or the *US Environmental Protection Agency (EPA)*. The most important techniques for the analysis of organic chemicals are based on gas chromatography-mass spectrometry, and procedures for inorganic chemicals include atomic absorption spectrometry or ion chromatography. Often equally good alternative techniques exist and can provide valuable confirmation of results. High-end technologies were not considered suitable for standardisation as they are not widely used by laboratories across Europe. To ensure consistency in measurements across different laboratories in different countries it was thought more important to use well-rehearsed laboratory techniques adequate for the purpose rather than those that are state of the art. With this view in mind the WP1 team recommended to agree on Minimum Required Performance Levels (MRPL) for all applicable methods.

Similarly, a multitude of analysis methods practiced in European laboratories was collected for biological threat agents. These methods differ largely in their complexity and their demands on sampling and sample preparation; they also differ in their suitability for the three purposes of analysis. Inter-laboratory comparisons were identified as an important factor for quality assurance; such initiatives exist in form of laboratory networks for identification analysis (NATO-SIBCRA, QUANDHIP) and for bio-forensic (EBLN). With similar arguments as the WP1 team, the biological experts also proposed to rather increase proficiency testing and to provide certified reference

material for method validation than to settle on a few standardised methods. The group also pointed towards a number of already existing standards from related areas like food and water quality or clinical analyses that could be modified to suit the analysis of environmental samples.

For radio-nuclear samples seven analytical techniques were selected:  $\gamma$ -spectrometry, gross  $\alpha$ - and gross  $\beta$ -counting techniques,  $\alpha$ -spectrometry and  $\beta$ -spectrometry coupled with radiochemistry, Inductively Coupled Plasma Mass Spectrometry, Thermo Ionization Mass Spectrometry and Secondary Ion Mass Spectrometry. Sample preparation was discussed and guidance given on points that need to be considered when analysing different matrices. In the RN-field many analytical methods were found to be standardised already, especially for the analysis of radionuclides in environmental matrices. Relevant forensic laboratories are also well-structured and many guidance documents from IAEA (International Atomic Energy Agency) exist. The main needs identified for RN threat agent analysis concern the analysis of radionuclides in biomedical matrices (e.g. urine, faeces), more regular proficiency tests for forensic laboratories (such as those organised by the Nuclear Forensics International Technical Working Group, ITWG), certified reference materials in environmental matrices (air particle filters, swabs) and accreditation according to existing standards for all of the above.

#### 3.1.4 Sample transport

Work packages 1-3 concluded their work with a review of existing regulations and procedures for the transport of CBRN samples within and between EU Member States. The findings for this part of the gap analysis were described in deliverables D1.3, D2.3 D3.3.

The transport of chemicals is regulated according to the *Recommendations for Transport of Dangerous Goods* published by the United Nations. Additionally, several international transport organizations like International Air Transport Association (IATA) have their own more specific rules. And in the special case of air transport, the captain of the airplane has still the right to refuse a shipment, even when all regulations are met.

Most of the rules for transport of dangerous goods have been established for significant quantities (typically hundreds of kilograms). For the transport of lower amounts, typically samples for analysis, the rules are less strict. While samples containing biological and radiological agents are always considered as dangerous goods, the regulations for chemical samples are less stringent in most cases. For example, the samples that are distributed for a Proficiency Test (PT) by the OPCW might contain small amounts of CWA's, but only the organic solvent is declared as a dangerous good. The OPCW has a special provision with IATA for transport of their samples and the SLAM team thought it advisable that such an arrangement is also in place for CBRN

incidents within the EU. The situation becomes more complicated when the identity of the samples is unknown. In that case screening experiments and risk assessment should determine whether the samples are considered as hazardous. It is possible to send a sample to a foreign laboratory when the concentration of the toxic compound is low and the sample is small.

The largest hurdle will be to obtain all relevant permits and licenses. In cases where dual use or strategically relevant compounds (e.g. reference standards) are involved, these processes can be very time-consuming. In the event of a CBRN incident it is advisable that the transfer of samples is coordinated or harmonized at the (inter)national level. Bilateral agreements between neighbouring countries as well as the establishment of networks of cooperating laboratories could facilitate this development within the EU.

The transport of category A and B<sup>1</sup> biological materials among European laboratories (across borders) is equally well-regulated through the UN guidelines mentioned above. Exemptions include packages that do not contain infectious material or that are unlikely to cause disease in humans or animals. These are not subject to dangerous goods regulations unless they meet the criteria for inclusion in another class.

The company *World Courier* is specialized in international transportation of biological and infectious material. In order to transport category A material shippers need to be certified. Thus, *World Courier* also provides a certification course in the transportation of biological and infectious material and dry ice by air. Laboratory networks across Europe are using this company for sample transport; packages can be delivered within 30 hours.

As other goods, transportation of radioactive material is regulated by international model regulations: transports on land Agreement on Dangerous Goods by Road/ Regulations Concerning the International Carriage of Dangerous Goods by Rail (ADR/RID), inland waterways, sea (International Maritime Dangerous Goods, IMDG) and air (IATA), but it has also to comply with specific requirements set forth in the State or international model regulatory documents.

When transporting CBRN samples from the site of an incident to an analytical laboratory, safety, security and preservation of evidence have to be considered. Most radioactive samples can be kept in their collection containers for shipment. However,

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<sup>1</sup> Category A infectious substances are capable of causing permanent disability, life threatening or fatal disease to humans or animals when exposure to them occurs. Category A infectious substances have two shipping names: "Infectious substances, affecting humans" (UN 2814) or "Infectious substances, affecting animals" (UN 2900). Category B infectious substances are infectious but do not meet the criteria for Category A. Category B infectious substances have the proper shipping name "Biological Substance, Category B" and the identification number UN 3373

these primary containers have to be packed inside another container that is certified for the shipment of such material. In all cases, the packaging and transportation need to satisfy legal, safety and security requirements.

Transportation of radioactive materials is strictly regulated and the requirements are fully described in IAEA documents. The availability of packaging and the existence of multilateral approvals between countries are key issues which have to be considered long before a RN incident or accident happens, especially if cross-border sample transportation is foreseen.

The following recommendations, based on the work from the Standing Working Group on safe transport of radioactive materials in the European Union, would facilitate the transport of radioactive materials between the member states:

- Harmonization of transport documentation to ensure that package certification issued by one Member State is accepted by all other EU countries
- Common methodology to achieve simultaneous certification of packaging
- Use of a unique format and a similar structure of the Safety Report for all types of packages
- Development of a mechanism to achieve simultaneous validation in the other Member States of the approval issued by the competent authority of the state of origin of the shipment and of a mutual recognition of transport licenses.

## **3.2 Gaps and needs for the analysis of mixed threat samples**

On the mere suspicion that an incident included deposition or release of highly toxic, contagious or radioactive material(s) or a combination thereof, maybe together with explosives, safe crisis management procedures must be applied in order to protect not only the public, but also the personnel involved in handling the crisis. This applies in particular to the steps of sampling, sample transport and handling at the laboratory.

### **3.2.1 Concept of the unknown sample**

Due to the insecure nature of unknown samples, they require a different approach than the samples discussed above, and they cannot be handled solely based on routine procedures for any one agent in isolation. Mixed/unknown samples rather require an iterative approach, in which results from one analysis are used to guide the selection of subsequent analyses. The efficiency of such iterative procedure will depend on the experience of the laboratory. Aspects of sample receipt at the laboratory and sample preparation need to be considered when planning and preparing for the analysis of mixed threat samples.

In the laboratory, analysis of CBRN mixed threat samples or “unknown samples” raises a series of safety and analytical challenges for the laboratory. How can, for example a complex mixed sample be investigated for the presence of chemical warfare agents if it may also contain biological and/or radiological substances?

The correct handling of a mixed sample requires multidisciplinary cooperation<sup>2,3</sup> and often a team of experts is established prior to receipt of any sample in order to discuss possible difficulties and to prepare for the analytical work. Not only must the safety of personnel be guaranteed but it is also important that the laboratory is not contaminated. This could happen if a radiological or biological sample is handled as if it only contained a chemical agent. Thus, the initial action taken upon receipt of the samples is crucial (see also Fig. 2). Moreover, unless sub-samples are taken for parallel analyses, the integrity of the sample throughout various sequential analyses must be secured as much as possible to prevent false or incomplete analytical results (see also Fig. 3). Analyses of putative mixed threat samples indicate that the analytical process is highly dependent on the nature of the material received and therefore, there is great need for flexibility.

The SLAM team found that more attention is needed to the issue of mixed/unknown CBRN samples in order to arrive at a systematically and scientifically evaluated recommended procedure for the analysis of such samples. Two principle approaches have been identified, sub-sampling for parallel analyses and sequential analysis for exclusion or separation of each CBRN component from one unique sample. All available information from field tests and indications of medical symptoms can aid proper planning of the analytical work.

Few publications are available addressing these complex issues and there is a lack of scientific work and evidence where methods handling mixed threat samples have been sufficiently evaluated with focus on safe handling and at the same time making it possible to analyse for all compounds present.

However, some nations have established their own in-house protocols including flow schemes for the analysis, but these are not compared and validated against other approaches. It can be foreseen that more research is needed to provide recommendations and standardised procedures and methods for receiving, handling and analysing mixed threat samples.

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<sup>2</sup> Analytical strategies for samples suspected to contain a mixture of CBRN agents, Martin Nygren, FOI, et al. IMPACT WP 800, Security Research, Preparatory Action on the enhancement of European Industrial potential in the field of Security Research,

<sup>3</sup> Assessment of Methods for Handling Mixed-Threat Environmental Samples, Robert Baur et al., Centers for Disease Control and Prevention, Atlanta, USA.



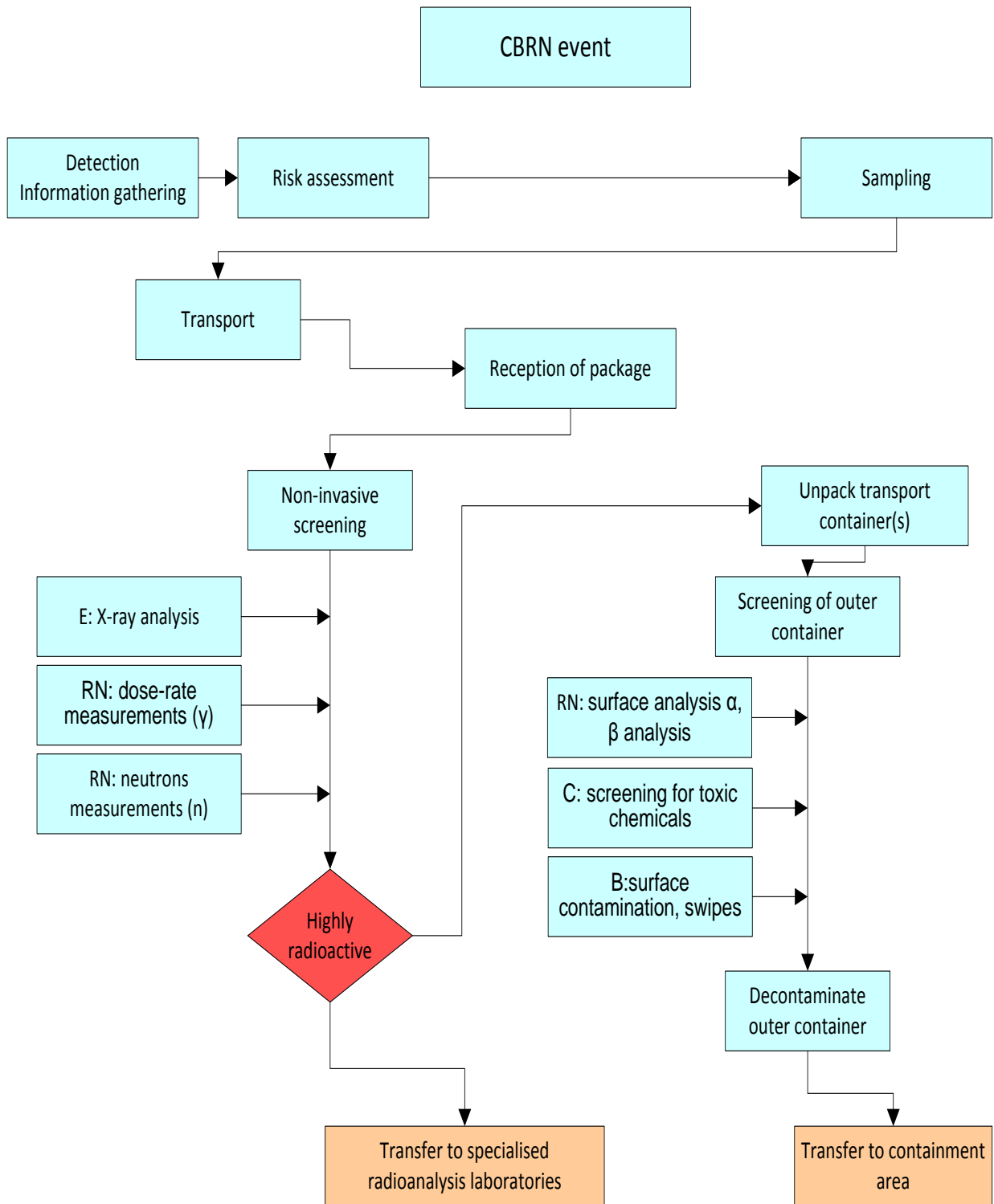


Figure 2. An example of handling of mixed threat samples at the reception area

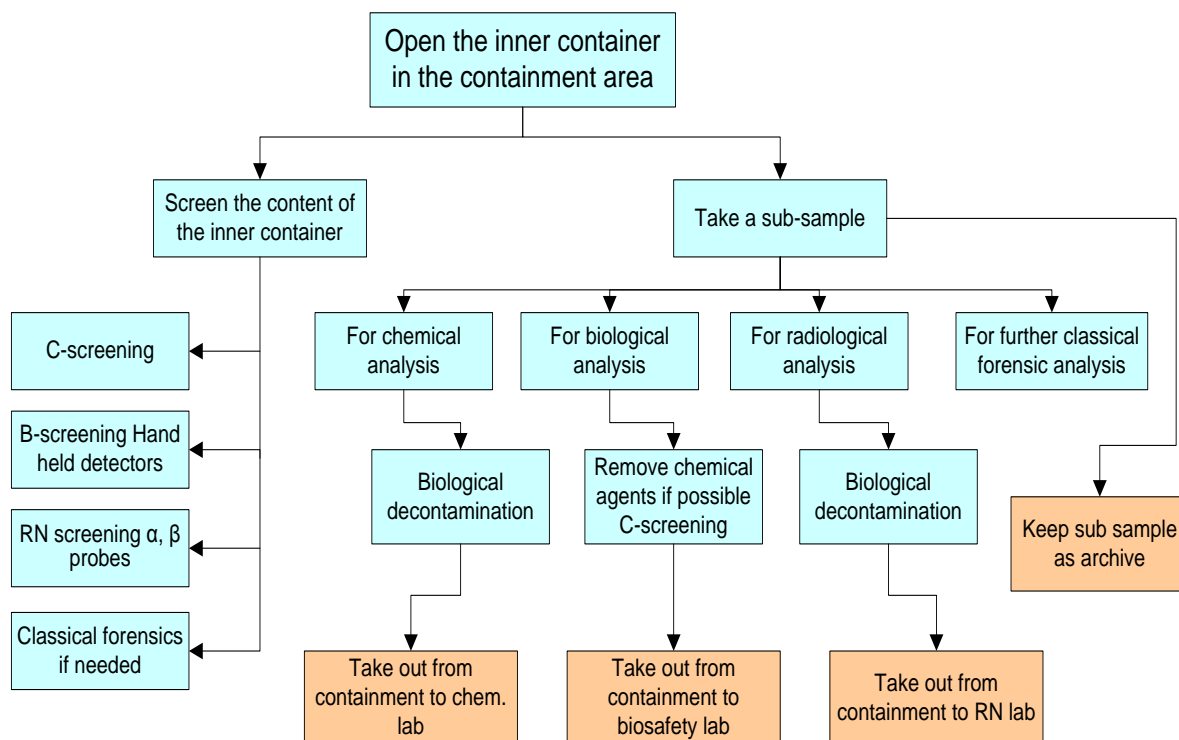


Figure 3. Example of handling mixed threat samples at the laboratory

### 3.2.2 Transport of unknown samples

The regulations for transport of dangerous goods are set up from a safety point of view. The safe transport of mixed threat samples, where the nature of the threat may be unknown or not easily defined, depends on a well-informed risk assessment. This requires knowledge and experience in evaluating all available information in a stressed and complex situation. Some risks can be screened for and excluded, while others cannot be ruled out quickly prior to transport, and have to be taken into account for the transportation. The risk assessment will often conclude that a sample is not a radiological hazard or is not explosive, but possibly infectious or toxic. The packaging used must be designed to minimize the potential for exposure of personnel or environment during transport. In addition, the packaging must ensure the integrity of the sample.

Due to the complex nature of transporting a mixed threat sample, prior agreements between authorities within a country or between countries are needed and advised in order to facilitate a smooth handling of the sample at the scene and to the laboratory. In the light of the extensive regulations concerning transports it would be advisable that bilateral agreements between neighbouring countries are discussed and in place beforehand. It would also be advisable that these transfers of samples are coordinated or harmonized at the (inter)national level. One way forward in this matter could be to

establish networks of cooperating laboratories within the EU. The need for administrative preparations can be discovered during joint planning or joint (table top) exercises.

### **3.3 Engaging member states in the discussion of standardisation issues**

One important aspect of project SLAM was to bring together representatives from EU MS authorities and laboratories in order

- i) to promote - in general - the interaction between neighbouring Member States on the issues of standardisation of laboratory analytical methods,
- ii) to complement and validate the findings of the SLAM project team and
- iii) to discuss - from the perspective of operational and strategic stakeholders - the relevance of the identified solutions as well as the feasibility of suggestions and recommendations for future standardisation activities.

In total three workshops were organized. After information on current and required capabilities had been collected from reference and accredited laboratories as well as from national regulatory bodies and authorities, the first workshop focused on the EU-wide comparison of methods and procedures established at European laboratories and on the development of common strategies and methodology. Issues such as surge capacity, involvement in routine monitoring and response at local and national levels were also discussed<sup>4</sup>.

The second workshop was organised as table top exercises whereby senior representatives from laboratories, relevant regulatory agencies and policy/decision-makers from EU Member State countries were engaged and encouraged to discuss participation in a pan-European network<sup>5</sup>. Scenarios were used to examine how different MS function at different levels regarding protocols and methodologies for quality control, forensic, quantitative and qualitative standards. The workshop also examined how MS engage with each other when managing a cross boundary issue.

The workshop discussions concluded that whilst countries have preparedness plans which clearly define the roles and responsibilities of different organisations and individuals within them, they are often not well rehearsed and do not always operate at the level of the decision maker. This may be due to a low perceived threat risk. From

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<sup>4</sup> This workshop was attended by 60 delegates from 15 different countries.

<sup>5</sup> 45 Delegates from 17 countries participated in this second workshop.

this, an identified opportunity was to prioritize multi-agency training exercises. In addition, laboratories, government agencies and intelligence services should all be involved in the preparedness planning.

There was a strong reluctance for laboratories to adopt a standardised set of methods. Having access to harmonised or standardised methods does not confer competence in using them and therefore labs would have the challenge to train staff. It was highlighted that a monitoring certification scheme (MCERTS) would allow labs to use their own methods with known recoveries of an analyte. MCERTS could provide the framework for laboratories to meet quality requirements as an application of ISO/IEC 17025.

It was observed that poor communication between sampling teams, the police, administrative staff and labs can result in poor quality or insufficient quantities of samples being collected rendering analysis meaningless. Attention should be given to ensuring good communication between different sectors during collection of samples, and accurate documentation to accompany the sample. Better standardisation would ensure information on how, where, why and when the sample was taken, and by whom. During a large incident involving the collection of different sample types, this would help a great deal with reporting and prioritising of work.

During a cross border incident, resilience can also be strengthened through harmonised documentation and reporting, presented consistently to avoid conflicting messages between countries. One option could be the development of a sample submission form. This may be met with resistance from some countries and so a checklist approach might be a better way to proceed on a European scale, where all the details are included in the checklist but the reporting organisation is not obliged to fill in all the fields.

During the third and last workshop the recommended solutions for harmonisation and standardisation activities were discussed with policy and decision makers from international organisations, EU and Member State authorities<sup>6</sup>. The solutions formulated by the SLAM team were based both on the technical needs and gaps identified and on the stakeholders' motivation to embrace harmonisation efforts and different levels of standardisation. The acceptance of standardisation activities can be influenced by a variety of factors like financial or staff resources, increased efficiency or other advantages.

Project SLAM identified a need for dedicated CBRN laboratories that are able to analyse samples in the event of a deliberate or accidental release. For the purpose of

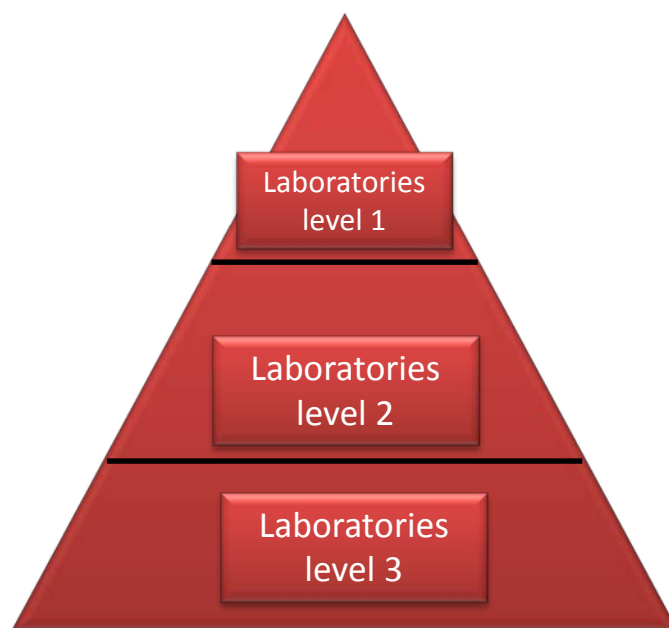
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<sup>6</sup> This workshop was attended by 34 delegates representing 11 countries and a number of EU authorities.

managing the different aspects of a CBRN incident, the team suggested a three-layered laboratory network (Figure 4):

- Level 1 laboratories having all resources, sophisticated equipment and reference compounds available; they are capable of performing analyses with high resolution and accuracy.
- Level 2 laboratories are equipped to handle large numbers of samples over a longer period of time. This kind of screening is often slower and requires higher sensitivity of the analytical method. These laboratories also have reference compounds in different matrices available.
- Level 3 laboratories can be commercial laboratories, which do not have the highest sophisticated equipment, but are capable of analysing large numbers of samples with low to medium resolution, less accuracy but high speed.

These three capability levels are not necessarily mutually exclusive, and there will be overlap between the activities and stakeholders involved throughout the course of an incident and the response phase.



*Figure 4. EU-wide laboratory network on three different levels.*

The division into different levels should be based on the analytical question or the purpose with the analysis (immediate incident response, post-incident monitoring and forensic use), not on analytical methods (provisional, confirmative, and unambiguous). It is, however difficult to label a laboratory according to a level, because analytical

processes are much more complex and the same laboratories might fit in two or three different levels. Because of the complexity and uncertainty when it comes to identifying three different laboratory levels those levels can be described and divided in different ways. The SLAM team suggested one possibility, not necessarily the correct/best way. This network would, however, not only allow for sharing of laboratory resources like analyses, but also for sharing of knowledge, material, training, and reference material.

In addition to such an EU-wide laboratory network the team also suggested

- To define minimum requirements for the first responder's capacity to detect CBRN substances. Minimum requirements for sampling and sample transport are also recommended for the first responders in order to be able to verify detector readings.
- That sampling performed by expert teams during the late response or recovery phase should follow EU best practice, while nationally developed recommendations are sufficient for other types of sampling teams.
- To standardise methods for sample transport through CEN, and to harmonize transport documentation in order to ensure that package certification issued by one Member State is accepted by all other EU countries.

Judging from the group discussions during the workshop delegates agreed to the suggestions for the way forward. It was also pointed out that - apart from the area of CBRN sample analyses - standardisation is also needed for the CBRN market.

### **3.4 Roadmap to standardisation**

WP6 organised a project-internal workshop during which external experts provided insight into the process of standardisation as well as inspiration from other already harmonized and standardized areas, i.e. international anti-doping analysis. This information was valuable for the choice of specific harmonisation/standardisation activities suggested in the roadmap and for the proposed schedule of the roadmap.

The suggested solutions formulated by the SLAM consortium were based both on the technical needs and gaps and on the motivation of the different operators to embrace various levels of standardisation. The motivation for laboratories to elaborate costly systems for standardisation is as always influenced by available resources. The most important question that influences the motivation for standardisation is whether the standardisation/harmonisation contributes to handling an incident more efficiently and as such contributes to the safety in Europe. The roadmap recommends that resources are used to catalyse the establishment of an EU-wide laboratory network.

This could be achieved by supporting existing European and national networks with initially project-linked funding. These networks shall be stimulated to address the following issues:

- All the relevant laboratories should be ISO 17025 accredited, and have access to certified reference material.
- The EU network should arrange interlaboratory comparisons for quality control for each CBRN letter.
- The network should address the issue of sample collection. Ideally, sample collection by expert teams should develop and follow an EU best practice.

The roadmap also recommends initiating a study that explores and identifies at EU and Member State level the customer relationship between EU, Member States, national and local stakeholders on one side and the laboratories active in CBRN incidents on the other side. This customer map should subsequently be used to identify an optimised set of drivers for the top-down aspect of a trans-European harmonisation process for laboratory services following a CBRN incident. In particular the top-down process should address the following issues:

- Methods for transporting samples should be standardised by CEN, and transport documentation should be harmonised to ensure that package certification issued by one Member State is accepted by all other EU countries.
- Minimum requirements for the first responder's capacity to detect CBRN substances should be defined and recommended.
- Minimum requirements for sampling and transport capacities should be defined and recommended in order to facilitate verification of detection readings performed by the first.

#### **4. Potential impact (including socio-economic impact and wider societal implications) and main dissemination activities and exploitation and foreground**

Harmonisation through the initiative of laboratory networks could be regarded as a bottom-up process, driven by motivated laboratories themselves. Harmonisation of identified and recommended laboratory/analytical activities could also be pursued through a top-down process initiated, controlled and financed by the customers, the owner of the process. Most likely future harmonisation will happen as a combination of both a top-down and a bottom-up process.

The most significant international customer for the report at hand is the European Commission with officials at all the Directorate Generals and at different mechanisms aiming at supporting the Member States' handling of CBRN incidents. The instruments for harmonisation are legislative acts and funding of European projects like framework projects or projects initiated directly by different Directorate Generals. Other potential international customers that are influential in the European perspective are organisations like WHO and IAEA.

There is also great fragmentation in crisis management systems and CBRN preparedness and resilience systems across Europe. Some EU Member States have chosen to centralise most of CBRN protection under one roof, creating governmental agencies and operational preparedness centres that cover a wide range of CBRN scenarios. Others have chosen a much more decentralised approach, where different agencies and institutions focus on different letters or different aspects of CBRN, alternatively according to different sectors such as health, law enforcement, rescue services, etc., without much coordination from above. Yet another complicating factor is the role of the military in case of a CBRN event, which also varies from Member State to Member State.

The implementation of the suggested laboratory network solution would open a unique opportunity for in-depth networking of key EU CBRN laboratories and would serve as basis for the creation of an EU wide laboratory network.

The motivation for the standardisation process is overall low among the first responders involved in the immediate incident response. Their motivation is driven by a functional conformity that could contribute to a more efficient and precise response, and therefore, a minimum requirement for sampling, detection and transport is recommended.

In addition, we recommend that sample collection in the late incident response and post incident response should follow EU best practice for expert teams, methods for





transporting samples should be standardised by CEN, and transport documentation should be harmonised to ensure that package certification issued by one Member State is accepted by all other EU countries.

By this, SLAM will contribute to and have an impact on European laboratory preparedness for CBRNE incidents also of cross-border nature. Consolidation of the European laboratory capability and harmonisation of the whole chain from sample collection to reporting and data interpretation will certainly contribute to and have an impact on the resilience of the European society.